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| APPLICATION NO.                                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------|
| 10/612,604  | 07/01/2003  | Wei Huang            | 011068-014-999                | 4803             |
| 20583   | 7590        | 09/07/2007           |                               |                  |
| JONES DAY<br>222 EAST 41ST ST<br>NEW YORK, NY 10017 |             |                      | EXAMINER<br>CHEN, STACY BROWN |                  |
|   |             |                      | ART UNIT                      | PAPER NUMBER     |
|   |             |                      | 1648                          |                  |
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|   |             |                      | 09/07/2007                    | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/612,604

Applicant(s)

HUANG ET AL.

Examiner

Stacy B. Chen

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-9 and 12 is/are allowed.
- 6) ☒ Claim(s) 1-4, 10 and 15-19 is/are rejected.
- 7) ☒ Claim(s) 11, 13 and 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 28, 2007 has been entered. Claims 1-19 remain pending and under examination.

2. The following rejections are withdrawn:

- The rejection of claims 11 and 12 under 35 U.S.C. 102(b) as being anticipated by Nijhuis *et al.* (*Current Opinion in Infectious Diseases*, 2001, 14:23-28, "Nijhuis") is withdrawn in view of Applicant's amendment. The claims do not recite the particular embodiment disclosed by Nijhuis, specifically, the mutations at positions 103 and 236. Therefore, the rejection no longer applies.
- The rejection of claims 1-10 and 13-19 under 35 U.S.C. 103(a) as being unpatentable over Nijhuis in view of Whitcomb (WO 99/61658) is withdrawn. Although Whitcomb discloses other mutations recited in the claims, there is no reasonable expectation of success that those mutations are predictive of viral fitness (replicative capacity).

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 10 and 15-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claim 1 (and dependent claims 2-4, 10 and 15-19) recite, “amino acid positions 98, 100, 101, 106, 108, 179, 181, 188, 190, 225, 226 or 236” [emphasis added]. The specification does not disclose an amino acid mutation at position 226.

***Claim Objections***

4. The claims are objected to for minor informalities:

- Claims 1-4, 10, 11 and 13-19 recite typographical errors, “the presence or absence or a mutation associated with impaired replication capacity at amino acid positions”... “or the amino acid sequence of said reverse transcriptase” [emphasis added].
- Claim 7 recites, “The method of claim 5, wherein mutation confers resistance”. Prior to the January 13, 2006 amendment, the claim read, “The method of claim 5, wherein said mutation confers resistance” [emphasis added]. If Applicant wishes to delete “said”, the claim should be appropriately indicated as amended according to 37 CFR 1.121.

- Claim 12 has an incomplete set of parentheses around the term “HIV-1”.

### *Conclusion*

5. Claims 5-9 and 12 are allowable. All claims are free of the prior art of record.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/ 8-28-2007  
Primary Examiner, TC1600